

MAY 30 2002



510(k) Summary
K021364
ArthroCare Corporation
Electrosurgery Wands

General Information

Submitters Name/Address: ArthroCare Corporation
680 Vaqueros Ave.
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person: Valerie Defiesta-Ng
Director, Regulatory Affairs

Phone Number: (408) 736-0224

Date Prepared: April 29, 2002

Device Description

Trade Name: ENTec® Plasma Wands

Generic/Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (21 CFR
878.4400)

Predicate Devices

ENTec Plasma Wands K014290; cleared on March 28, 2002

Product Description

The Wands are bipolar, single use, high frequency electrosurgical devices designed for a variety of ENT applications.

Intended Use

The ENTec Plasma Wands are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

Substantial Equivalence

This Special 510(k) proposes a modification in labeling for the Wands, which were previously cleared under K014290 on March 28, 2002. The indications for use, technology, principle of operation, packaging, and sterilization parameters of the Wands remain the same as in the predicate cleared 510(k)s.

Summary of Safety and Effectiveness

The Wands, as described in this submission, are substantially equivalent to the predicate, unmodified Wands. The proposed modification in labeling is not a substantial change or modification, and does not significantly affect the safety or efficacy of the devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2002

Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Re: K021364

Trade/Device Name: ENTec® Plasma Wands
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 29, 2002
Received: April 30, 2002

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: ENTec® Plasma Wands

510(k) Number: K 021364

Indications for use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021364